

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1 and 9 have been amended. The claim amendments are supported by the disclosure at page 11, lines 23–26; page 13, line 30, through page 14, line 1; page 14, lines 10–14 and 18–21; and in Example 2 (disclosing species recited in claims 180–183). Claims 1–11, 13–16, 145–183, and 185 are pending, with claims 145–183 being withdrawn.

In response to the election of species requirement, applicant hereby elects SEQ ID NO: 23 as the BC loop region sequence, SEQ ID NO: 34 as the AB loop region sequence, and SEQ ID NO: 67 as the FG loop region sequence. Pending claims reading on SEQ ID NO: 23 include claims 1–7, 9–11, 14–16, 145–183, and 185. Pending claims reading on SEQ ID NO: 34 include claims 1–5, 9–10, 14–16, 145–183, and 185. Pending claims reading on SEQ ID NO: 67 include claims 1–6, 8–11, 14–16, 145–179, 181–183, and 185.

The rejection of claims 1–11 and 13–16 for obviousness-type double patenting over claim 1 of U.S. Patent No. 6,673,901 to Koide (“Koide”) in view of U.S. Patent No. 6,818,418 to Lipovsek et al. (“Lipovsek”) is respectfully traversed. While claim 1 of Koide is generic to the presently claimed subgenus, neither Koide nor Lipovsek teach or suggest the presently claimed subgenus. Indeed, neither of these references alone, nor the combination thereof, teach any modified loop region that affords a polypeptide having nuclear receptor binding activity. Given the breadth of the genus encompassed by claim 1 of Koide (it is potentially infinite), and the absence of any disclosure in Koide or Lipovsek concerning polypeptide monobodies that bind to a nuclear receptor, the obviousness-type double patenting over claim 1 of Koide in view of Lipovsek is improper and should be withdrawn.

The rejection of claims 1–11, 13–16, 180–183, and 185 under 35 U.S.C. § 112 (2nd para.) for indefiniteness is respectfully traversed in view of the above amendments to claims 1 and 9. With regard to the objection to the use of the language “combinations thereof,” applicant submits that this language is not unclear merely because it encompasses the use of modified loop sequences for two or more of the six identified loop sequences. This is explicitly disclosed, for example, in Table 1, where species having modified BC and FG loops are described. The nomenclature of the various loops and beta strands is overcome by the above amendments. This rejection should therefore be withdrawn.

The rejection of claims 1–11, 13, and 14 under 35 U.S.C. § 102(b) for anticipation by U.S. Patent No. 5,922,676 to Pasqualini et al. (“Pasqualini”) is respectfully traversed.

Pasqualini describes a polypeptide that corresponds to residues 1416 to 1509 of fibronectin. The PTO’s position is that the fibronectin fragment disclosed in Pasqualini is a monobody of the present invention, because it differs from SEQ ID NO: 2 by deletion of 2 amino acids at the N-terminal tail.

Claim 1 does not read on Pasqualini, because claim 1 recites that the “at least one loop region sequence comprises an amino acid sequence which varies by deletion, insertion, or replacement of at least two amino acids from a corresponding loop region of SEQ ID NO:2 or SEQ ID NO:3.” Pasqualini fails to teach or suggest this feature of claim 1. Moreover, the PTO has failed to demonstrate that the fragment described by Pasqualini “exhibits nuclear receptor binding activity.” Because Pasqualini is deficient in both these respects, the rejection of claims 1–11, 13, and 14 as anticipated by Pasqualini should be withdrawn.

The rejection of claims 1–11, 13–15, and 185 under 35 U.S.C. § 102(b) for anticipation by WO 98/56915 to Koide (“Koide II”) is respectfully traversed.

Koide II discloses various polypeptide monobodies derived from the 10th Fn3 domain of fibronectin. The PTO has admitted that Koide does not teach a polypeptide that exhibits nuclear receptor binding affinity, but has taken the position that Koide II nevertheless anticipates the claimed invention because the polypeptides of Koide II and those claimed here have a genus-species relationship. Applicant respectfully disagrees.

The mere existence of a genus-species relationship is an insufficient basis for rejecting claims under §102(b). It is well established law that a genus will anticipate a species within that genus only if one of ordinary skill in the art would immediately envisage the claimed species from the disclosed genus. *See In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962) (genus describing 20 compounds describes each species within the meaning of section 102(b)); *In re Schaumann*, 572 F.2d 312, 316-17, 197 USPQ 5, 9 (prior art disclosure embraces such a limited number of compounds closely related to one another in structure that it “provides a description of those compounds just as surely as if they were identified in the reference by name”). In this case, the genus disclosed in Koide II is exceptionally large, covering any variants of the loop regions of the wild-type tenth fibronectin type III domain that allow for binding to an unspecified bind partner. Given the

breadth of the binding partners and the breadth of variants encompassed by Koide II (and the absence of any species that fall within the claimed subgenus), one of ordinary skill would not immediately envisage the subgenus that is presently claimed, let alone species encompassed thereby.

For this reason, the rejection of 1–11, 13–15, and 185 as anticipated by Koide II is improper and should be withdrawn.

The rejection of claims 1–11, 13, 14, and 185 under 35 U.S.C. § 102(e) for anticipation by U.S. Patent No. 6,818,418 to Lipovsek et al. (“Lipovsek”) is respectfully traversed.

Lipovsek relates to proteins that include a fibronectin type III domain having at least one randomized loop. The PTO has admitted that Lipovsek does not teach a polypeptide that exhibits nuclear receptor binding affinity, but has taken the position that Lipovsek nevertheless anticipates the claimed invention because the polypeptides of Lipovsek and those claimed here have a genus-species relationship.

For substantially the same reasons noted above, the mere existence of a genus-species relationship is an insufficient basis for rejecting claims under §102(e). Given the breadth of the genus encompassed by Lipovsek (and the absence of any species that fall within the claimed subgenus), one of ordinary skill would not immediately envisage the subgenus that is presently claimed, let alone species encompassed thereby. For this reason, the rejection of 1–11, 13, 14, and 185 as anticipated by Lipovsek is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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